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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,504	10/19/2001	Steven J. Siegel	P-9565-US	3358

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EXAMINER	
FUBARA, BLESSING M	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
01/16/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/046,504	SIEGEL ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3,4 and 6-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4 and 6-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt request for extension of time, request for continued examination under 37 CFR 1.114, amendment and remarks filed 10/17/07. Claims 1, 3 and 4 are amended. Claims 1, 3, 4 and 6-10 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1017/07 has been entered.

2.

Response to Arguments

Previous rejections that are not reiterated herein have been withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 4, 6 and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The method of claim 4, whereby the method comprises "(a) dissolving haloperidol and biodegradable polymer consisting essentially of selected from the group ...in acetone" is confusing because it is not made known by the claim language what the biodegradable polymer is consisting essentially of and what is being selected from the group consisting of. Clarification is respectfully requested. However, for examination purposes, the polymer is assumed to be selected from the group consisting of polylcatide and lactide-co-glycolide copolymer.

Also, claim 4 in (a) is confusing in that (a) selects the biodegradable polymer from " polylactide or and lactide-co-glycolide," the use of and in that case is appropriate and it appears that the presence of "or" before the "and" is a typographical error. Correction is respectfully requested.

Claim 10 depends from claim 7. Claim 7 treats patients by surgically implanting the composition of claim 1 in which the active agent is haloperidol and which an antipsychotic drug. Thus, it is unclear whether in claim 10, a different antipsychotic drug is further administered orally to the patient or it is the haloperidol that is further administered orally to the patient.

Clarification is respectfully requested.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al., "A poly(D,L-lactide-co-glycolide) microsphere depot system for delivery of haloperidol," in Journal of Controlled Release 55 (1998) 203-212.

7. Cheng describes haloperidol-loaded biodegradable poly(D,L-lactide-co-glycolide) (PLG) microsphere (abstract), a 10% haloperidol was achieved (section 3.3 at page 208). "Surgically implantable drug delivery" is in the preamble and represents the intended use of the delivery system while the body of the claim fully defines the claimed composition/product/device. The difference between the claims and Cheng is that the claims recite a range of 20-40% of haloperidol being fabricated into the polymer while Cheng uses 10%. However, it is said on page 209, left column at line 6 that a drug content of from 14.6 to 23.9% can be loaded onto the PLG microspheres. Therefore, taking the teaching of Cheng, one of ordinary skill in the art at the time the invention was made would have reasonable expectation of success to formulate haloperidol loaded biodegradable poly(D,L-lactide-co-glycolide) (PLG) microsphere in which the drug load is 10% or from 14.6 to 23.9%.

8. Claims 1, 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al., "A poly(D,L-lactide-co-glycolide) microsphere depot system for delivery of haloperidol," in Journal of Controlled Release 55 (1998) 203-212 in view of Domb et al. ("Degradable Polymers for Site-Specific Drug Delivery," in polymers for Advanced Technologies, Vol. 3, pp. 279-292, 1992.

9. Cheng is discussed above as rendering obvious claims 1 and 3. Cheng acknowledges that haloperidol, an antipsychotic drug, is used to treat psychosis such as schizophrenia by oral dosage forms and also as long acting depot injections (section 1). Cheng administers the haloperidol by injecting the composition as a depot. But, implantation/implant reads on depot resulting from depot injections, and it is known to use degradable polymers to deliver drugs to target sites of interest ad described by Domb and carries the advantage that implants are used as site specific drug delivery routes. Therefore, taking the teachings of the references together, one of ordinary skill in the art at the time the invention was made would have reasonable expectation of success to administer the haloperidol antipsychotic drug by implanting it to a site in the schizophrenic subject that would provide sustained release of the antipsychotic agent for a more effective treatment of the condition.

10. Claims 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al., "A poly(D,L-lactide-co-glycolide) microsphere depot system for delivery of haloperidol," in Journal of Controlled Release 55 (1998) 203-212 in view of Sidman (US 4,450,150) .

11. Cheng prepares the haloperidol loaded biodegradable poly(D,L-lactide-co-glycolide) (PLG) microsphere by solvent evaporation (section 2.2). Cheng does not cast the haloperidol dissolved in the solvent in a mold so that Cheng differs from the invention by not molding the haloperidol-polymer solution. However, it is known that implants that deliver drugs to target sites are molded by compressing or injecting the drug formulation as disclosed by Sidman (column 9, lines 8-12; column 10, lines 51-52; column 18, line 29). Therefore, taking the teachings of the references together, one of ordinary skill in the art at the time the invention was

made would have reasonable expectation of success to shape the haloperidol antipsychotic drug loaded polymer by injection molding or compression molding to provide a product that would be successfully implanted into the site in the schizophrenic subject that would provide sustained release of the antipsychotic agent for a more effective treatment of the condition.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600